UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES, EX REL. DR. SUSAN NEDZA,	)	
	)	
Plaintiff-Relator,	)	NO. 15-CV-6937
	)	
v.	)	JUDGE JORGE L. ALONSO
	)	
AMERICAN IMAGING MANAGEMENT, INC., ANTHEM INC., ANTHEM HEALTH PLANS OF KENTUCKY, INC., ANTHEM HEALTH PLANS OF NEW HAMPSHIRE, INC., ANTHEM HEALTH PLANS, INC., ANTHEM INSURANCE COMPANIES, INC., BLUE CROSS OF CALIFORNIA, BLUE CROSS AND BLUE SHIELD OF GEORGIA, INC., BLUE CROSS AND BLUE SHIELD HEALTHCARE PLAN OF GEORGIA, COMMUNITY INSURANCE CO., COMPCARE HEALTH SERVICE INSURANCE CORP., EMPIRE HEALTHCHOICE HMO, INC., EMPIRE HEALTHCHOICE ASSURANCE, INC., HEALTH FIRST HEALTH PLANS, INC., HMO COLORADO, INC., HMO MISSOURI, INC., BLUE CROSS OF IDAHO CARE PLUS, INC., BLUE CROSS BLUE SHIELD OF MICHIGAN MUTUAL INSURANCE COMPANY, BLUE CROSS AND BLUE SHIELD OF NORTH CAROLINA, MODA HEALTH PLAN, INC., PRIORITY HEALTH, PROVIDENCE HEALTH PLAN, PROVIDENCE HEALTH ASSURANCE, REGENCE BLUECROSS BLUESHIELD OF OREGON, REGENCE BLUECROSS BLUESHIELD OF UTAH, REGENCE BLUESHIELD, REGENCE BLUE SHIELD OF IDAHO, ASURIS NORTHWEST HEALTH, AND PACIFICSOURCE COMMUNITY HEALTH PLANS.	)	JURY TRIAL DEMANDED
	)	
	)	SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT
	)	
Defendants.	)	

SECOND AMENDED COMPLAINT

Plaintiff-Relator Dr. Susan Nedza, through her attorneys, on behalf of the United States of America (the "Government"), for her Complaint against American Imaging Management, Inc.

("AIM"), Anthem Inc., and the "Defendant Insurance Plans": Anthem Health Plans of Kentucky, Inc., Anthem Health Plans of New Hampshire, Inc., Anthem Health Plans, Inc., Anthem Insurance Companies, Inc., Blue Cross of California, Blue Cross and Blue Shield of Georgia, Inc., Blue Cross and Blue Shield Healthcare Plan of Georgia, Community Insurance Co., Compcare Health Service Insurance Corp., Empire Healthchoice HMO, Inc., Empire Healthchoice Assurance, Inc., Health First Health Plans, Inc., HMO Colorado, Inc., HMO Missouri, Inc., Blue Cross of Idaho Care Plus, Inc., Blue Cross Blue Shield of Michigan Mutual Insurance Company, Blue Cross and Blue Shield of North Carolina, Moda Health Plan, Inc., Priority Health, Providence Health Plan, Providence Health Assurance, Regence Bluecross Blueshield of Oregon, Regence Bluecross Blueshield of Utah, Regence Blueshield, Regence Blue Shield of Idaho, Asuris Northwest Health, and Pacificsource Community Health Plans (collectively, "Defendants") alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and claims Defendants and/or their agents or employees caused to be made in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 et seq. ("FCA").

2. This *qui tam* case is brought against Defendants for knowingly defrauding the federal Government in connection with the federally funded Medicare Advantage ("MA") healthcare program, 42 U.S.C. § 1395w-21 *et seq*.

3. Through the acts described in greater detail below, Defendants have submitted and caused to be submitted fraudulent claims to the federal healthcare program. Each submission was a false or fraudulent claim in violation of the federal False Claims Act.

4. The Defendant Insurance Plans all contracted with the government under the Medicare Advantage program, certifying as a mandatory and material condition of their participation that they would provide the same coverage to Medicare beneficiaries as the beneficiaries would receive if they were direct Medicare participants, and certifying with each request for payment by the government of premiums that they were doing so.

5. American Imaging Management, Inc. (which does business as AIM Specialty Health) ("AIM") provides pre-authorization review for its client health insurance companies for many services requested by medical providers.

6. Defendant Insurance Plans contracted with AIM for its Utilization Management ("UM") review process. AIM promised Defendant Insurance Plans that it would deny requests at specific high rates to hit cost savings goals. AIM fulfilled that promise by intentionally structuring the UM review process to systematically avoid compliance with the applicable mandatory rules regarding what procedures and treatments were covered by Medicare.

7. A utilization management process that appropriately implemented Medicare's coverage rules would result in denial rates for certain services (i.e. diagnostic imaging services) between approximately 0.5% and 1.5%. In contrast, according to AIM's internal documentation, the more restrictive AIM UM review process resulted in denial rates for those services as high as 5% to 9%.

8. Defendant Insurance Plans knew that AIM's determinations were intentionally not in compliance with Medicare coverage standards, resulting in the systematic wrongful denial of coverage requests.

9. AIM's wrongful ploys to deny coverage included the following:

a. Instead of using Medicare Rules to evaluate requests, AIM reviewed pre-authorization requests based on internal rules called the AIM Guidelines that were not based on Medicare Rules, were significantly more stringent than Medicare Rules, and were created not to comply with Medicare requirements, but rather to save insurance plans money.

b. AIM's UM computer algorithms included provisions to refuse pre-approval with no basis in the internal AIM Guidelines, let alone Medicare Rules, or any medical evidence.

c. AIM prohibited its nurse and physician reviewers from making more than one follow-up contact to get necessary additional information related to a pre-authorization request in direct contradiction of Medicare Rules requiring multiple contacts to get information.

d. When AIM's UM review process failed to produce enough denials and cost savings to meet their contractual targets, the AIM UM computer algorithm was turned off and AIM categorically delayed or declined all requests for pre-authorization without regard for medical need.

e. AIM automatically and without notice denied requests if the medical provider failed to contact AIM within one business day of being requested to do so.

f. AIM fax machines were set to stop printing after ten pages of medical documentation were received from medical providers, so the most critical patient information was often not included in AIM's review.

g. AIM did not provide the actual reason for denial to the patient in its denial letters, but rather misrepresented the reason as being based on the Medicare Rules.

10. Collectively, Defendants falsely certified compliance with Medicare's substantive and procedural rules to obtain billions of dollars of government premium payments. Defendants falsely certified that they would follow all Medicare rules in determining what care Medicare beneficiaries would receive, all the while knowing that they were using an unlawful scheme of pre-authorization designed by AIM to delay and deny care in violation of Medicare Rules. As a result, the government paid for coverage the Medicare beneficiaries did not receive; the Medicare beneficiaries received less medical care than they were legally entitled to; the beneficiaries suffered delay and denial of medical procedures, increased financial costs, inferior medical care, and in many instances, physical and mental suffering; while AIM, its clients, the Defendant Insurance Plans, and parent company Anthem, all enjoyed excess and illegal profits.

11. The federal False Claims Act (the "FCA") was originally enacted during the Civil War. Congress substantially amended the Act in 1986 – and, again, in 2009 and 2010 – to enhance the ability of the United States Government to recover losses sustained as a result of fraud against it. The FCA was amended after Congress found that fraud in federal programs was pervasive and that the FCA, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments would create incentives for individual whistleblowers with knowledge of fraud against the Government (called relators) to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

12. The FCA prohibits, inter alia: (a) knowingly presenting or causing to be presented to the federal government a false or fraudulent claim for payment or approval; (b) knowingly making or using, or causing to be made or used, a false or fraudulent record or statement material to a false or fraudulent claim; (c) conspiring to knowingly present or cause to be presented to the federal government a false or fraudulent claim for payment or approval; and (d) knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government. 31 U.S.C. §§ 3729(a)(1)(A)-(C), and (G). Any person who violates the FCA is liable for a civil penalty of up to $11,000 for each violation committed on November 2, 2015 or before (and up to $21,916 for each violation committed after November 2, 2015), plus three times the amount of the damages sustained by the United States. 31 U.S.C. § 3729(a)(1).

13. The FCA allows any person having information about an FCA violation to bring an action on behalf of the United States, and to share in any recovery. The FCA requires that the Complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the government time to conduct its own investigation and to determine whether to join the suit.

14. Defendants' false and fraudulent statements and conduct alleged in this Complaint violated the federal False Claims Act, 31 U.S.C. § 3729 *et seq*.

15. Plaintiff-Relator Dr. Susan Nedza seeks through this action to recover all available damages, civil penalties, and other relief for the FCA violations alleged herein in every jurisdiction to which Defendants' misconduct has extended.

II. PARTIES

16. The Relator, Dr. Nedza, served as Chief Medical Officer and a member of the executive team at AIM from July 2012 until January 2015. Among other things, Dr. Nedza oversaw the AIM Clinical Affairs Group and was responsible for development of clinical guidelines and regulatory compliance for Medicare programs, including compliance with Medicare policies and regulations. Dr. Nedza voluntarily terminated her employment with AIM after it became apparent to her that in spite of her efforts, AIM was not willing to comply with Medicare policies and regulations.

17. Prior to her position at AIM, Dr. Nedza was Vice President of Strategic Clinical Solutions at Health Circles, LLC, where she served as a member of the executive team and led the clinical team that built evidence-based clinical tools for healthcare providers.[1] From 2008 to 2010, she was Vice President of Clinical Quality and Patient Safety Strategy, and Medical Director, Clinical Practice Solutions, at the American Medical Association.

18. From 2003 to 2008, Dr. Nedza served as the Chief Medical Officer for Region V and as a Medical Officer in the Special Program Office in the United States Department of Health and Human Services ("HHS") at the Centers for Medicare and Medicaid Services ("CMS"). Among her duties was working with insurance companies on Medicare coverage policies.

19. Dr. Nedza holds an M.B.A. from the Kellogg Graduate School of Management of Northwestern University and an M.D. from the Stritch School of Medicine at Loyola University.

[1] Evidence-based clinical tools are clinical algorithms that enable doctors to effectively and efficiently manage patient care.

20. Plaintiff the United States of America is the real party in interest in this matter. The United States through HHS administers the Medicare program. Title XVIII of the Social Security Act, 42 U.S.C. §1395-1395kkk-1.

21. Defendant AIM is a specialty health benefits management corporation organized under the laws of the state of Illinois. AIM is a wholly-owned subsidiary of Anthem. AIM makes health insurance coverage determinations in the areas of radiology, cardiology, oncology, specialty drugs, and sleep medicine for over 48 health plans with approximately 38 million covered members.

22. Defendant Anthem, Inc. ("Anthem," formerly known as WellPoint) is a health benefits company organized under the laws of the state of Indiana. Anthem is AIM's parent company (since 2007) and is the parent company of National Government Services, a Medicare Administrative Contractor ("MAC") hired by CMS to perform certain services, including writing regional guidelines for Medicare coverage called Local Coverage Determinations ("LCDs"). Anthem serves approximately 73 million individuals through its affiliated companies, including more than 40 million individuals enrolled in one of its health insurance plans. One in eight Americans receives coverage for their medical care through Anthem's affiliated plans.

23. Anthem is also the parent company of the following Defendant Insurance Plans that hired AIM to increase profits by utilizing the AIM UM review process: Anthem Health Plans of Kentucky, Inc., Anthem Health Plans of New Hampshire, Inc., Anthem Health Plans, Inc. (serving Connecticut), Anthem Insurance Companies, Inc. (serving Indiana), Blue Cross of California, Blue Cross and Blue Shield of Georgia, Inc., Blue Cross and Blue Shield Healthcare Plan of Georgia, Community Insurance Co. (serving Ohio), Compcare Health Service Insurance Corp. (serving Wisconsin), Empire Healthchoice HMO, Inc., Empire Healthchoice Assurance,

Inc., HMO Colorado, Inc., and HMO Missouri, Inc. Defendant Insurance Plans also include non-Anthem insurance plans: Blue Cross of Idaho Care Plus, Inc., Blue Cross Blue Shield of Michigan Mutual Insurance Company ("BCBS Michigan"), Blue Cross and Blue Shield of North Carolina ("BCBS North Carolina"), Health First Health Plans, Inc., Moda Health Plan, Inc., Priority Health, Providence Health Plan, Providence Health Assurance, Regence Bluecross Blueshield of Oregon, Regence Bluecross Blueshield of Utah, Regence Blueshield, Regence Blue Shield of Idaho, Asuris Northwest Health, and Pacificsource Community Health Plans.

III. JURISDICTION AND VENUE

24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

25. Venue is proper in this district under 31 U.S.C. § 3732(a) because AIM transacts business in this district and committed a number of the acts complained of in this district.

26. Although the issue is no longer jurisdictional after the 2009 amendments to the FCA, to Relator's knowledge, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint, as those concepts are used in 31 U.S.C. § 3730(e). To the extent there may have been a public disclosure under 31 U.S.C. § 3730(e), Relator is the original source of the allegations herein because: (1) prior to any public disclosure, she voluntarily disclosed to the government the information on which her allegations are based; and (2) she has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions, and she voluntarily disclosed that information to the United States Attorney for the Northern District of Illinois before filing, in accordance with 31 U.S.C. § 3730(b)(2).

IV. APPLICABLE LAW

A. The Medicare Program

27. Medicare is a federally-funded health insurance program that covers certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease. The Medicare program is administered through the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

28. The Medicare program has four parts: Part A, Part B, Part C and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, such as services provided to Medicare patients by physicians, laboratories, and diagnostic testing facilities. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

29. "Traditional Medicare" (Parts A and B) operates on a "fee-for-service" basis, meaning that fiscal intermediaries that contract with CMS to administer the program pay hospitals and physicians directly for each service they provide to a Medicare beneficiary.

30. Medicare Part C provides the same benefits to Medicare beneficiaries as traditional Medicare, but does so under a managed care model, rather than the traditional fee-for-service model. Under Part C, rather than pay providers directly, Medicare pays private managed care insurance plans (known as "Medicare Advantage" or "MA" plans) a capitation rate (a fixed amount per member per month) and those plans are responsible for paying providers for services. The monthly capitation rate is based on the beneficiary's geographic location, income status, gender, age, and health status.

B. Medicare Advantage

31. MA insurance plans profit by keeping the healthcare costs they approve lower than the amount the government pays. The insurance plans are legally required to "assume the full financial risk" for the cost of required care. 42 U.S.C. §1395w-25(b). Accordingly, the more medical care that is denied, the greater the profit realized by the plan.

32. To prevent the improper denial of care for the sake of profits, plans must certify as a condition of MA participation and payment to provide all care that would be provided under traditional fee-for-service Medicare, and also to follow all Medicare Rules that require fair individualized coverage determinations based Medicare's own coverage rules. To participate in MA and to receive MA payments, each insurance plan must certify to CMS that it will and does comply with the Medicare statute, Medicare regulations, and all Medicare non-regulatory guidance, procedures, and policies regarding coverage and treatment of beneficiaries (collectively the "Medicare Rules"). 42 U.S.C. § 1395w-27; 42 CFR § 422.101; 42 CFR § 422.504(a). Compliance with "all the applicable requirements and conditions" is expressly "material to performance of the contract" between CMS and the MA plans. 42 CFR § 422.504(a); 42 U.S.C. § 1395w-27. The certification also includes the explicit commitment that MA insurance plans will comply with the "False Claims Act." 42 CFR § 422.504(h)(1). These certifications are part of the contract each MA insurance plan signs with CMS. 42 U.S.C. § 1395w-27.

33. While MA insurance plans are permitted to subcontract, the MA insurance plan "maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract" with CMS. 42 CFR § 422.504(i)(1); 42 CFR § 422.562(a)(3); CMS, Medicare Managed Care Manual § 11.110.1. Further, every subcontract must require that "any services or other activity performed by" a subcontractor (here AIM) "comply with the MA

organization's contractual obligations" with CMS, 42 CFR § 422.504 (i)(3)(iii), and that subcontractors will follow all "Medicare laws, regulations, and CMS instructions," 42 CFR § 422.504(i)(4)(v). MA insurance plans also pledge to monitor the performance of all subcontractors "on an ongoing basis." 42 CFR § 422.504(i)(4)(iii). In short, each MA insurance plan is fully responsible for compliance with Medicare Rules for its beneficiaries and cannot outsource or subcontract away Medicare compliance.

34. Substantively, the insurance plans certify that they will and do follow Medicare Rules that require them to: (a) provide all Medicare benefits and abide by Medicare Rules in making any coverage determination; (b) develop a fair procedure for making individualized coverage determinations based on a specific patient's medical needs; and (c) implement an effective compliance program that ensures coverage determinations are made in accordance with Medicare Rules.

1. MA plans must provide coverage for all Medicare benefits as defined by CMS.

35. The "Basic Rule" of the Medicare Advantage program is that insurance plans must provide beneficiaries with all of the services and benefits required under traditional Medicare. 42 U.S.C. § 1395w–22(a)(1)(A); 42 C.F.R. § 422.100; 42 C.F.R. § 422.101(a); 42 C.F.R. § 422.504(a) (MA plans must provide "[i]n a manner consistent with professionally recognized standards of health care, all benefits covered by Medicare"); CMS, Medicare Managed Care Manual § 4.10.2. Thus, MA insurance plans, like traditional fee-for-service Medicare, must provide all services and benefits that are "medically necessary" as defined by Medicare Rules. 42 U.S.C. § 1395w–27(g)(1).

36. Medicare beneficiaries are entitled to health care services that are "reasonable and necessary for the diagnosis or treatment of illness or injury" and some preventive services. 42 U.S.C. § 1395y(a)(1); CMS, Medicare Managed Care Manual § 4.10.2. This includes diagnostic imaging services. 42 U.S.C. § 1395x(s).

37. CMS (through the Secretary of Health and Human Services) "has the authority to make determinations about which specific items and services, within categories, may be covered under the Medicare program." CMS, Medicare Managed Care Manual § 4.10.2. CMS defines what is "reasonable and necessary" healthcare for Medicare coverage through national rules—called National Coverage Determinations ("NCDs"), 42 U.S.C. §§ 1395y, 1395ff(1)(B); 42 C.F.R. § 422.101(b)(1)—and regional rules called Local Coverage Determinations ("LCDs"), 42 U.S.C. § 1395ff(f)(2)(B); 42 C.F.R. § 422.101(b)(3). (CMS hires Medicare Administrator Contractors, including one of Anthem's subsidiaries, to perform a number of services, including writing LCDs.) An insurance plan participating in Medicare Advantage must make coverage decisions in compliance with NCDs, 42 U.S.C. § 1395y(l); 42 CFR § 422.101(b)(1), 42 C.F.R. § 422.109, and LCDs, 42 U.S.C. § 1395y(l); 42 C.F.R. § 422.101(b)(3), and all "Medicare manuals and instructions," 42 CFR § 422.101(b)(2). See also CMS, Medicare Program Integrity Manual, Ch. 13.

38. MA insurance plan coverage decisions must be based on "coverage criteria no more restrictive than original Medicare's national and local coverage policies" and must consider "the enrollee's medical history." CMS, Medicare Managed Care Manual, § 4.10.16. Any service "must be covered by every MA plan" if "coverage is consistent with general coverage guidelines included in original Medicare regulations, manuals and instructions." CMS, Medicare Managed Care Manual, § 4.90.1.

2. MA plans must process coverage requests based on complete information about an individual's medical situation.

39. Insurance plans must also have effective procedures in place to make proper individualized determinations of Medicare coverage. 42 C.F.R. § 422.566(a); 42 U.S.C. § 1395w-22(g). Insurance plans must have fair procedures to make coverage determinations. Those procedures must provide "individual medical necessity determinations." CMS, Medicare Managed Care Manual, § 4.10.16; 42 C.F.R. § 422.112(a)(6)(ii) (A MA insurance plan's written standards, including for "utilization management," must "allow for individual medical necessity determinations"). MA insurance plan coverage decisions must also fully consider "the enrollee's medical history." CMS, Medicare Managed Care Manual, § 4.10.16.

40. While CMS does not forbid pre-authorization reviews (i.e., the type of service Defendant AIM provides) in the MA program, Medicare Rules prohibit any pre-authorization process that limits care or is a barrier to care. "MA Plans may not implement utilization management protocols that create inappropriate barriers to needed care." CMS, Medicare Managed Care Manual, § 4.110.1.1.

41. Further, whenever an MA insurance plan "expects to issue a partially or fully adverse medical necessity … decision," Medicare's coverage guidelines require that the decision "must be reviewed by a physician or other appropriate health care professional" familiar with "Medicare coverage criteria" before such a decision is issued. 42 C.F.R. § 422.566(d).

3. MA insurance plans are obligated to continually audit and monitor their operations and subcontractors for violations of Medicare Rules.

42. MA insurance plans must "[a]dopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements." 42 C.F.R. § 422.503(b)(4)(vi). An effective compliance program

must include routine monitoring, audits, and timely and reasonable inquiries when non-compliance is discovered; taking corrective actions when necessary; and voluntarily self-reporting fraud and misconduct. 42 C.F.R. § 422.503(b)(4)(vi)(A)-(G).

43. The duty to monitor includes a specific and explicit duty for MA insurance plans to monitor subcontractors. CMS, Medicare Managed Care Manual § 11.110.2 (subcontractors must be "monitored on an ongoing basis and formally reviewed by the organization at least annually"). "In the areas of grievance processing or utilization management, for example, monitoring may be more or less continuous." Id.

44. Fundamental to each CMS contract in the MA program, and each payment under those contracts, is the certification that the insurance plan (and any other entity to which it outsources) will provide Medicare compliant coverage determinations based on a fair review of claims and provide all benefits required under Medicare. Although the Defendant Insurance Plans outsourced certain review and determination functions to AIM, the Defendant Insurance Plans cannot escape responsibility for following Medicare Rules by outsourcing to AIM.

V. ALLEGATIONS

A. AIM contractually promised to deny medical care and increase insurance plans' profits.

45. Insurance plans hired AIM to cut costs and increase profits by denying care to Medicare beneficiaries. AIM's sales pitch and business model was simple. AIM frequently promised, upon pain of financial penalty, to deliver cost savings. Every month, AIM reported to each of its insurance plan clients the number of procedures denied and thus the amount of dollars saved.

46. In AIM's marketing to prospective clients, and in many of its contracts with insurance plans, AIM promised to deny requests at specific rates to hit cost savings goals. AIM

and the Defendant Insurance Plans knew that the targeted denial rates and cost savings could not be achieved without wrongly denying coverage in violation of Medicare Rules.

47. AIM routinely ensured the insurance plans that the cost savings they realized would be at least a multiple of the cost of AIM's services. AIM also agreed to hold harmless certain insurance plans for any shortfall in the guaranteed cost savings.

48. To win insurance plan business, AIM promised concrete cost savings tied to denial rates as high as 5%-9%. AIM, however, knew that if it complied with Medicare Rules, the denial rate for certain services (i.e., diagnostic imaging services) should have been only 0.5% to 1.5%.

49. AIM's business model and contracts created powerful incentives for it to deny coverage requests, regardless of merit or medical need, to meet denial rate targets. This is especially true for the lucrative MA insurance plan clients, whom AIM charged as much as three times the rate for commercial plans for its services.

50. On information and belief, AIM never failed to meet a contractual denial target for any insurance plan with whom it contracted.

B. AIM's UM review process.

51. In brief, AIM's UM review process worked as follows: (1) a medical provider, such as a treating doctor, sent AIM a request for pre-authorization for insurance coverage (that is, insurance approval before the medical service is provided). (2) AIM decided whether the plan should approve or deny the pre-authorization request. (3) AIM communicated its determination to the insurance plan, medical provider, and/or the MA beneficiary. (4) The insurance plan then adopted AIM's decision and approved or denied the request accordingly.

52. Among other medical procedures, AIM reviewed requests for: Computerized Tomography ("CT"), Echocardiography, Magnetic Resonance Angiograms ("MRA"), Magnetic Resonance Imaging ("MRI"), and Positron Emission Tomography ("PET") scans, and sleep studies.

53. AIM's utilization management ("UM") review process, however, operated to manufacture request denials and cost savings in three steps. And, in none of the steps did AIM apply the mandated Medicare Rules.

54. First, a medical provider submitted a request with basic information to AIM either via telephone to one of AIM's three call centers, or online through AIM's Provider Portal. At this step, AIM used a simplistic computer algorithm, based on its own internal standards and not Medicare Rules, to process and review requests without regard for Medicare Rules and medical appropriateness.

55. Second, if the request was denied by the algorithm, the medical provider had to speak with an AIM nurse reviewer who further considered the request, but used the same AIM algorithm as well as AIM's "MD/RN tool." The "tool" was a set of resources and rules on AIM's intranet based on the internal AIM Guidelines, rather than on Medicare Rules. AIM's nurse reviewers thus evaluated requests without relying on the Medicare Rules.

56. Third, if the request for pre-authorization was not approved by the nurse reviewer, the medical provider had to speak with one of AIM's physician reviewers who again considered the request relying on AIM's internal rules in the MD/RN tool rather than the Medicare Rules. At this step, if the request was not approved, AIM formally denied the pre-authorization of services.

57. When AIM denied pre-authorization for a medical procedure, the insurance plan likewise denied pre-authorization. Without pre-authorization, Medicare (through the insurance plan) would not cover the cost of the procedure. As a practical matter, therefore, AIM denied the Medicare beneficiary both insurance coverage and access to a medical procedure deemed necessary by the beneficiary's treating physician.

58. Under traditional fee-for-service Medicare, beneficiaries are not subjected to formal pre-authorization requirements before they can receive diagnostic imaging procedures. But under the MA program, insurance plans hired AIM to limit costs and increase profits. As alleged below, AIM's preauthorization practices violated Medicare Rules and created improper barriers to care deemed necessary by the treating physician.

C. Mechanics of fraud: The Defendants' scheme intentionally and wrongly denied requests for approval.

59. To achieve its contractual commitments of high denial rates and profit targets, AIM designed its UM review process both to ignore Medicare Rules and to produce improper denials of requests for preauthorization. AIM's foremost goal—and business imperative—was to hit the denial rates promised in its contracts with the insurance plans at all costs.

1. AIM periodically categorically refused to approve requests—with no basis beyond contractual promises—to increase denials and hit profit targets.

60. When AIM's regular UM review process failed to produce enough denials (and cost savings for insurance plans), AIM categorically declined the initial approval of requests to increase denial rates.

61. As alleged above, normally the first step in AIM's UM review process was to use its algorithms to evaluate a request based on the basic information a provider submitted online or

via the call center. Requests that did not meet AIM's narrow, self-generated criteria were not approved and were subjected to additional review; the provider had to speak with a nurse reviewer about the specific patient and medical needs.

62. To ensure it met the contractual guarantees of cost savings, AIM monitored the denial rates by type of procedure and by client insurance plan on a weekly basis. Weekly reports included the "WOT Transfer and Impact Rate" and "Impact and Transfer Trend" reports, run for each client, each week. If the internal reports indicated that AIM was not denying a sufficient number of requests to a hit contractual target for a particular plan, AIM executives ordered that AIM categorically decline all requests for a specific diagnostic procedure for that specific insurance plan (e.g., all CT scans for a specific plan). The instruction came from AIM leadership, including Randy Hutchinson, Julie Thiel, and/or Michael Backus. When ordered, the AIM computer algorithm was turned off, and AIM simply refused to approve all such requests for pre-authorization in the first step of its UM review process. Rather than AIM's typical first step approval rate of 70-80%, every request was denied, and put in the queue for AIM nurse review, regardless of medical appropriateness. AIM referred to this process as "implement 100% transfers," or "turn off approvals."

63. AIM's sole basis for turning "off" the algorithm was to increase denial rates in order to meet contractual denial targets. Although some requests were ultimately approved upon further review, the blanket "turn off" significantly increased denials by imposing additional steps and delay. The manipulation of the AIM UM review process and refusal to approve medically necessary requests was done without regard to medical necessity or Medicare Rules and solely to meet AIM's contractual targets.

64. Moreover, since at least 2012, AIM has worked to develop a computerized review process with more complex algorithms that would allow a more sophisticated manipulation of denials. One of AIM's goals was to create an algorithm "thermostat" that would allow AIM to arbitrarily set the desired approval rate for each test, and for each client, regardless of medical necessity. AIM sought to replace the crude process of turning the algorithms off completely in order to meet contractual targets. The "thermostat" would be set to meet certain contractual targets for denial of requests, with no consideration of medical appropriateness and in complete disregard for Medicare Rules. It was an effort to computerize and facilitate AIM's fraudulent denials.

65. By the time Dr. Nedza left AIM in early 2015, AIM had yet to implement the new algorithms with "thermostat" controls, but it was continuing to work on the project with outside contractors.

66. Even without "thermostat" controls, AIM's algorithms were designed to manipulate the UM review process to increase denials and profits. The algorithms were indifferent to compliance with Medicare Rules. Indeed, the algorithms were so flawed that they included provisions to refuse pre-approval without any basis in either the internal AIM Guidelines, or the Medicare Rules.

67. AIM's algorithms were developed in-house and were extremely crude and limited applications. The algorithms could only handle questions with "yes" or "no" responses, calculate simple scores, and process three questions for any particular request (i.e., an initial question and two follow up questions about the condition of the patient). This was inadequate to properly implement even the AIM Guidelines, let alone the Medicare rules for coverage, or to determine medical appropriateness.

68. Moreover, AIM assigned the task of writing and updating the algorithms to staff with no medical background or experience. AIM also failed to subject the computer algorithms to any testing or verification to ensure that they evaluated requests in compliance with the Medicare Rules.

69. Despite knowing the limitations of the computer algorithms, AIM refused to correct these problems. Instead, AIM continued to use the computer algorithms to deny requests and subject medically justified requests to further delay and review where they could be weeded out and denied through additional methods.

70. Thus, whether the AIM algorithms were turned on or turned off (when AIM's process failed to generate enough denials), AIM's algorithms made its UM review process noncompliant with the Medicare Rules.

71. AIM's UM review process created "inappropriate barriers to needed care" of the sort prohibited by Medicare. See CMS, Medicare Managed Care Manual, §4.110.1.1 (2016).

2. AIM limited contact with medical providers and set secret, arbitrary deadlines to deny requests for "case aging" rather than upon any medical basis.

72. AIM also increased denial rates by prohibiting its nurse and physician reviewers from making more than one follow-up contact to get necessary additional information related to a pre-authorization request. The "one contact limit" contradicts Medicare Rules which require "reasonable and diligent efforts to obtain all necessary medical records and other pertinent information within the required time limits." CMS, Medicare Managed Care Manual § 13.70.7.1; CMS, Best Practices and Common Findings Memo #2 from 2012 Program Audits, (July 30, 2013) (criticizing MA plans for audit findings where they "failed to conduct appropriate outreach to obtain needed medical documentation" and requiring "at a minimum 2 attempts to contact a

provider's office during the provider's business hours on 2 different days and at different times of the day" for appropriate outreach); CMS, Updated Guidance on Outreach for Information to Support Coverage Decisions (February 22, 2017).

73. AIM acknowledged internally that its one-call policy violated CMS rules, but did not change its practices for years. As of November 14, 2014, Jennifer Dullum, AIM's Vice President of Compliance, wrote that AIM staff "currently make one call out for Medicare Advantage (MA) cases." Ms. Dullum identified four prior instances by specific date going back to 2012, where CMS indicated that such policies and practices violate Medicare Rules, and that insurance plans must contact beneficiaries multiple times if necessary. Further, AIM was aware—through CMS audits of the Defendant Regence Idaho and Defendant PacificSource plans 2014—that AIM's specific practice violated Medicare Rules.

74. AIM also increased improper denials by arbitrarily denying requests in instances when the medical provider failed to respond to AIM within one business day of a contact. AIM referred to this improper policy as "case aging." AIM failed to inform treating providers of the time limit it imposed on preauthorization requests. If the treating provider failed to call within one business day of a message being left, AIM simply sent the pre-authorization request to a physician reviewer to stamp "denied."

75. AIM's leadership, specifically including CEO Brandon Cady, endorsed the case aging rule as a very effective way to increase denials cost-effectively, without increasing AIM staffing. Denying requests for case aging provided a significant cost savings for AIM and increased profits at the expense of patient care. Denials based on an arbitrary case-aging policy violated Medicare Rules that require insurance plans to implement procedures that make individualized determinations based on medical necessity and appropriateness. 42 CFR

§422.112(a)(6)(ii); 42 CFR § 422.566(d); CMS, Medicare Managed Care Manual, § 4.10.16 and § 13.40.1.1. Case aging also contradicts Medicare's requirement that insurance plans must make reasonable and diligent efforts to obtain all necessary information, including medical records and other pertinent documentation, from the beneficiary's provider. CMS, Updated Guidance on Outreach for Information to Support Coverage Decisions (February 22, 2017)

76. "Case aging" denials violated both the patient's right to a fair and full review and Medicare's physician review rules.

3. AIM systematically, arbitrarily, and secretly curtailed the submission and review of patient medical information.

77. Although medical providers were permitted to submit medical documentation to AIM, and such documentation was often necessary to evaluate the propriety of the request, starting in or around 2012 or 2013, AIM set an arbitrary and undisclosed limit of ten pages that it would receive from medical providers via facsimile. After ten pages, the fax machines at AIM simply stopped printing the incoming medical records. As a result, critical medical information was often not included in AIM's review.

78. AIM implemented the ten-page limit to save staff time spent reviewing medical records, as well as money spent on fax machine ink and paper. AIM never informed medical providers about the ten-page limit (as it also never did with the one business day rule). Without knowledge of the arbitrary ten-page limit on faxed records, medical providers could not even know to select the ten most pertinent pages to submit.

79. AIM's refusal to consider medical documentation beyond the first ten pages of a patient's medical record violated AIM's duty to make individualized coverage determinations based on an individual patient's medical history. CMS, Medicare Managed Care Manual, §

4.10.16. It also violated Medicare Rules that require an insurance plan to provide a fair process to make decisions based on medical need. 42 C.F.R. § 422.566(a); 42 U.S.C. § 1395w-22(g). And it was a flagrant violation of the requirement that a decision be based on "all relevant documentation that is submitted with the claim." 42 CFR § 410.32.

80. AIM's secret rule arbitrarily limiting the review of medical documentation denied coverage to MA beneficiaries in violation of the Medicare Rules.

4. AIM denied coverage for Medicare requests based on its restrictive internal rules, while ignoring Medicare Rules.

81. Even in instances when AIM considered a Medicare request on the medical merits, AIM ignored requirements regarding the scope of Medicare coverage. All Medicare Advantage insurance plans promised CMS that they would provide "all services that are covered" by traditional Medicare, 42 CFR § 422.101(a); 42 CFR § 422.504(a); 42 U.S.C. § 1395w–22(a)(1)(A), including diagnostic imaging services, 42 U.S.C. § 1395x(s).

82. MA plans must cover medical services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. 42 U.S.C. § 1395y(a)(1)(A)-(B). Determinations of reasonable and necessary services required application of the coverage rules in CMS National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). The NCDs and LCDs "specify under what clinical circumstances an item or service is considered to be reasonable and necessary." CMS, Medicare Program Integrity Manual § 13.1.3. When AIM rigged UM review for the Defendant Insurance Plans so that requests for authorization were wrongfully denied, it caused the Defendant Insurance Plans (with their knowledge or reckless disregard) to violate Medicare Rules.

83. The Defendant Insurance Plans, by contracting with AIM, knowingly failed to provide the full coverage guaranteed by Medicare. "AIM client contracts clearly delineate use of AIM Guidelines as the source for the medical necessity determination," instead of Medicare Rules. AIM Guidelines and Clinical Script Process (December 17, 2009). AIM and the Defendant Insurance Plans thus contracted for the intentional violation of Medicare Rules. In addition, when necessary to satisfy contractual targets, AIM ignored its own rules, as discussed above, in order to increase denial of preauthorization requests.

84. Accordingly, AIM denied Medicare beneficiaries the right to an individualized review based on medical need. CMS, Medicare Managed Care Manual, § 4.10.16; 42 C.F.R. § 422.112(a)(6)(ii); 42 C.F.R. § 422.566(a); 42 U.S.C. § 1395w-22(g). It also violated Medicare's requirement that insurance plans provide all medically necessary care, as determined by CMS.

85. When AIM's nurse and physician reviewers evaluated coverage requests, they used AIM's "MD/RN tool." The MD/RN tool is a set of resources on AIM's intranet comprised of different tabs for each insurance plan. Each of tab included both the AIM Guidelines (which are the same for all insurance plans, MA or commercial) and any substantive additional terms ("medical policies") of the individual insurance plan. The MD/RN tool did not include the content of Medicare Rules, LCDs or NCDs. While AIM took the time to implement insurance plan-specific rules to deny requests, AIM long refused to develop the infrastructure or resources to implement Medicare's coverage rules.

86. The MD/RN tool did not incorporate Medicare coverage rules. The tool did include a link to the CMS website, which theoretically might have allowed an AIM nurse or physician reviewer to examine Medicare Rules if they were willing and able to take the time to do so. However, in practice, AIM expected each reviewer to process such a high volume of

requests that even if a reviewer wanted to find, review and apply the relevant Medicare Rules, he or she did not have time to assess whether an NCD or LCD or other Medicare rule required approval of a request. To do so, reviewers would have had to locate, read, and apply the pertinent Medicare Rules for each Medicare Advantage request. This was not possible for AIM staff given the time constraints and production quotas, as Julie Thiel told Dr. Nedza and other AIM executives on multiple occasions in 2013 and 2014. AIM knowingly refused to hire enough reviewers to spend that much time on any single request.

87. Indeed, AIM was fully aware that its staff did not consider Medicare Rules because AIM regularly monitored the "click rate" (i.e., how often a nurse or physician reviewer clicked on the links) for the links to the CMS website on the MD/RN tool, and the rate was very low.

88. Instead of using Medicare Rules, on the occasions that AIM actually did review pre-authorization requests on the merits, it did so based on internal rules called the AIM Guidelines. AIM developed the AIM Guidelines to deny requests and reduce costs for commercial insurance plans, which are not bound by Medicare Rules.

89. The AIM Guidelines were not based on Medicare Rules, were more stringent than Medicare Rules, and were created not to comply with Medicare requirements, but rather to save insurance plans money. The following are some examples of imaging benefits that were denied under AIM Guidelines contrary to Medicare Rules:

a. Denying requests for CT scans where such scans would have been medically appropriate under Medicare Rules;

b. Requiring an X-ray to be performed prior to approving a request for imaging where no such prerequisite existed under Medicare Rules;

c. Requiring physical therapy prior to approving an imaging request where no such requirement existed under Medicare Rules;

d. Denying requests for imaging of adjacent sites where no such limitations existed under Medicare Rules; and

e. Denying requests for bilateral imaging where no such limitation existed under Medicare Rules.

90. AIM implemented its own Guidelines to construe coverage more narrowly regardless of any relevant (or conflicting) Medicare Rules. In fact, AIM's official policy was that the AIM Guidelines trumped any contrary Medicare Rules. AIM's policy stated that AIM would deny claims when the AIM Guidelines supported denial, even when "not consistent with" a Medicare Rule "in a NCD or LCD."

91. As AIM explained on April 4, 2013 to Dr. Richard Frank, the National Staff Vice President and Medical Director for Medicare Advantage of Defendant Anthem, AIM's policy was explicitly to deny a request for services that was a "Covered Benefit" under Medicare if the request was not consistent with the "AIM Guidelines."

92. Proper reliance on Medicare's coverage rules for the relevant preauthorization requests results in denial rates between about 0.5% and 1.5%. In contrast, according to AIM's internal estimates, reliance on the more restrictive AIM Guidelines and UM review process resulted in denial rates as high as 5 to 9%.

5. AIM falsified mandatory Medicare notices to Medicare beneficiaries.

93. When AIM issued a formal Medicare Notice of Denial of Medical Coverage to the Medicare Advantage beneficiary and provider, AIM was required to provide a "detailed explanation" and "description of the applicable Medicare coverage rule." CMS, Form

Instructions for the Notice of Denial of Medicare Coverage (or Payment) CMS-100003-NDMCP; CMS, Medicare Managed Care Manual, § 13.90.6 (requiring the use of CMS-10003-NDMCP); 42 U.S.C. §1395ff(a)(4). See also 42 U.S.C. § 1395w-22(g)(1)(B).

94. To cover up its baseless rejection of Medicare requests and prevent improper denials from being challenged, AIM did not provide the actual reason for denial to the patient in its denial letters. Instead, AIM quoted language from an AIM Guideline and misrepresented the language from the AIM Guidelines as being from the Medicare Rules.

6. AIM established rules to increase denials, trained, encouraged and directed staff to deny requests, and developed a "culture of no," re-enforced by financial incentives.

95. At each step of the UM review process, AIM established rules and conducted training to increase the denial of requests and to drive up profits.

96. AIM's rules barred AIM staff from working with medical providers to approve meritorious requests. In the first step of the UM review process, AIM's call center staff were not medically-trained professionals and had no training on (or even access to) either the AIM Guidelines or the Medicare Rules. These call center staff were forbidden from offering suggestions or re-running the algorithms based on additional information to assist providers in getting even a meritorious request approved by AIM's rigged system.

97. Similarly, AIM directed nurse reviewers and physician reviewers to not ask medical providers follow-up questions that could lead to approval of requests. Thus, even if an AIM nurse or physician reviewer knew—or believed—the request might be medically appropriate, if the provider did not give just the right information about the patient to fit the request into one of AIM's narrow approval criteria, AIM denied the request.

98. AIM also trained its call center staff, nurses, and physicians on how to systematically deny requests. AIM had an education team of three individuals, one for each call center, who reported to Senior Vice President Julie Thiel and were responsible for training the nursing review staff. Likewise, AIM had a group of three physicians to give ongoing training to physician reviewers.

99. These teams used trainings, including lectures and case studies, to ensure nurse and physician reviewers knew what excuses and fact patterns to use to deny requests for pre-authorization, and to do so even when AIM's Guidelines suggested that reviewers had discretion to approve the request. AIM also required its reviewers to rely heavily on AIM's requirements, such as requiring physical therapy before a certain imaging test, even when the requirements were inconsistent with the Medicare Rules.

100. Although AIM did not provide any ongoing training on compliance with Medicare Rules, AIM regularly trained reviewers on changes to the AIM Guidelines and taught reviewing staff the updated ways to deny requests. AIM staff were given scenarios and hypotheticals of patients and told how to respond and deny requests. The training was coupled with testing to ensure quality control and uniformity of denials between reviewers.

101. AIM trained its reviewers to be even more restrictive than its own already restrictive Guidelines. Although some of AIM Guidelines suggest that requests for pre-authorization for certain scans should be scrutinized, AIM instructed its reviewers to instead simply deny those requests. For example, while the AIM Guidelines indicated that "simultaneous ordering of multiple examinations may subject these examinations to more intensive levels of review," AIM reviewers simply did not approve requests for simultaneous orders.

102. Similarly, AIM instructed its physician reviewers to use the AIM Guidelines to deny requests for simultaneous orders of tests on many adjacent body parts (such as upper and middle back scans). Several physician reviewers objected to this directive and complained to Dr. Nedza that it forced the patient to visit the doctor twice, on separate days, with separate co-pays, and without medical justification. This both increased patient expense and unnecessarily delayed a necessary diagnostic procedures.

103. AIM further reinforced its rules and expected denial rates through rigorous tracking of data and financial bonuses tied to outcome metrics. The cost of each review in nurse and physician expenses was tracked in the "AIM Cost Per Case" report.

104. Likewise, AIM tracked detailed metrics about every individual person on its review staff. AIM calculated requests processed per day, average review time, and denials for every individual.

105. Individual performance metrics were used as a basis for AIM staff performance evaluations and bonuses.

D. Defendants knowingly and intentionally flouted Medicare Rules.

106. During her employment with AIM, Dr. Nedza repeatedly attempted without success to get AIM to adopt a review system that was compliant with the Medicare Rules.

1. AIM studied and quantified the impact of continuing to violate Medicare Rules, but decided it was too expensive to follow the law.

107. AIM knew that it did not review requests based on Medicare Rules, and that its Guidelines and process were not based on or designed to meet Medicare's requirements. Further, by at least 2008, AIM also knew its UM review process violated Medicare Rules, because by that point, CMS had cited Anthem in an audit related to cases adjudicated by AIM.

108. During, Nedza's tenure, AIM went so far as to quantify the impact of its own noncompliance. In 2013, AIM medical staff members Dr. Thomas Power and Deborah Lamm reviewed 164 Medicare patient files that AIM had denied and determined that 160 should have been approved under Medicare policy. This means AIM properly denied only 4 of the 164 cases, or 2.5% of the denials. The findings of this study were widely discussed among top AIM management, including Dr. Nedza, CEO Brandon Cady, Julie Thiel (Senior VP of Clinical Programs), Randy Hutchinson (COO), and Christopher Kurtenbach (VP of Operations).

109. In an experiment with Medicare compliance from January to April 2014, discussed in detail below, AIM confirmed that if it followed Medicare Rules its denial rate would drop to near 0%. Under its business model, AIM could not sell a review process that led to a near 0% cost savings for insurance plans. High denial rates were what AIM was selling to its customers.

110. Even AIM's own marketing materials demonstrated that AIM knew how far out of compliance its UM review process was with Medicare Rules. In preparing 2013 promotional materials to sell AIM services to the Health Care Services Corporation (a very large Blue Cross Blue Shield affiliate), AIM's draft materials stated that review of requests under Medicare Rules would result in a denial rate of just 0.5%, a rate far below what AIM promised to deliver under its UM review process. AIM's UM review process prevented 5% - 9% of requests depending on the state. These promotional materials were developed by AIM's business team, with review and approval from AIM's leadership including Anne Pukstys (VP Client Management), Christiane Shah (VP Solutions Management), and Randy Hutchinson (COO). These marketing materials promised the insurance plan a higher cost savings with AIM's UM review process, but also

admitted the "compliance risk" of using AIM's review system on Medicare Advantage requests, particularly because some denials "will likely be overturned by CMS."

2. AIM executives openly and continually discussed the decision to violate Medicare rules.

111. The choice to violate Medicare Rules in search of profits was openly discussed by AIM, its parent company Anthem, and the Defendant Insurance Plans. From 2012 to 2015, the period of Dr. Nedza's employment, AIM's internal communications and documentation reflect a conscious disregard for the Medicare Rules. AIM's top executives openly discussed its non-compliance with Medicare Rules, legal risks, and failure to implement a Medicare-compliant system at the highest levels of corporate leadership. At numerous executive committee meetings and on other occasions, Dr. Nedza personally participated in discussions of Medicare noncompliance with top AIM leaders including CEO Brandon Cady, Joel Cesario (CFO), James Chow (former COO), Randy Hutchinson (COO), Michael Backus (CSO), and Julie Thiel (SVP) throughout 2012, 2013, and 2014.

112. Medicare noncompliance was likewise continually discussed nearly weekly at Physician Leadership Committee meetings and regular Quality Committee meetings in 2012, 2013, and 2014. AIM executives further discussed Medicare noncompliance in countless emails during this time as AIM refused to follow Medicare Rules and put in place a Medicare-compliant review process.

113. On several occasions during her tenure at AIM, Dr. Julie Thiel, AIM's Senior Vice President of Clinical Programs urged AIM to stop inappropriately denying requests for MA pre-authorizations, including in an October 15, 2013 email to other AIM executives, including COO Randy Hutchinson and VP Christiane Shah. On that occasion, she proposed that AIM simply approve all Medicare requests to stop "incorrectly denying" Medicare requests.

114. Similarly, as part of her continuous efforts to reform the AIM process, Dr. Nedza repeatedly spoke and emailed with AIM's top leadership, including Julie Thiel (SVP), James Chow (former-COO), Randy Hutchinson (COO), and Brandon Cady (CEO), about AIM's violation of Medicare Rules and about her concerns regarding AIM's failure to make the changes necessary to bring AIM into compliance with the Medicare Rules.

115. Top AIM leadership was fully aware of AIM's systematic violation of the Medicare requirements. Following a decision in late 2014 for Anthem insurance plans to increasingly use AIM services for Medicare requests, even AIM's Vice President of Compliance, Jennifer Dullum, remarked that AIMs UM review process risked landing insurance plan clients in jail.

116. At least through the end of 2014, AIM's top executives openly discussed the fact that AIM was not complying with Medicare Rules, and they nonetheless chose to continue AIM's noncompliance. The problem, as AIM COO Randy Hutchinson put it, was that Medicare compliance "will impact the value" of AIM to the insurance plans, and AIM's very business model. AIM decided it was more profitable to keep the Medicare business by defrauding the government.

3. By 2014, AIM was so concerned about the risk of continued noncompliance that it began to experiment with Medicare compliance.

117. In 2012 and 2013, AIM executive leadership considered routing all Medicare Advantage requests to trained nurse reviewers who would actually follow and implement Medicare Rules. However, AIM CEO Brandon Cady rejected that idea because it was too expensive. AIM refused to provide the staff and time needed to separately and accurately assess Medicare-Advantage requests, and refused to give up the profits it could generate through the existing AIM UM review process.

118. Then, out of continuing concern about the consequences of Medicare non-compliance, for a short period from January to April 2014, AIM tried switching the MA requests from the standard AIM UM review process to a review process that only denied MA requests based on specific Medicare-compliant criteria. AIM made this temporary change for certain MA client insurance plans—including BCBS of North Carolina, BCBS of Michigan, and Health First Health Plans in Florida. The resultant denial rates dropped to close to 0%. As a result, the business side of AIM, led by Randy Hutchinson, with the agreement of CEO Brandon Cady, and Christiane Shah, VP of solutions Management, pushed back against the trial review process. As a result, AIM returned to using the standard AIM UM review process to deny Medicare requests, with the resultant return to excessive denial rates and increased profits.

119. After the failed Medicare compliance trial in early 2014, AIM faced increasing pressure from its client insurance plans to develop review processes that actually followed Medicare Rules. Defendant BCBS of North Carolina, for example, was audited by CMS in late 2013 or early 2014 and criticized for having erroneous request denials (made by AIM), which had to be reversed on appeal. BCBS of North Carolina complained to AIM and demanded changes.

120. Similarly, in early 2014 a CMS audit cited Defendant Regence Blue Shield of Idaho for noncompliance because AIM denied requests without contacting medical providers for patient information or giving providers sufficient opportunity to submit supporting documentation with a request. Another AIM client, Defendant PacificSource, was cited by CMS for the same practice later in 2014. CMS condemned AIM's practice of making only one call to a treating provider to seek information, rather than the multiple attempts CMS requires in order to

give beneficiaries a fair review. As a result of the CMS findings, Defendants Regence and PacificSource both complained to AIM about its noncompliant practices.

121. These complaints from insurance plans were a departure from their past approval of AIM's noncompliant UM review process. Before 2014, for example, Defendant BCBS of North Carolina, including its former medical director Dr. Eugenie Komives, had expressly approved AIM's UM review process. They authorized AIM to deny denying requests based on AIM's internal guidelines and not Medicare Rules. Moreover, like all AIM client insurance plans, these insurance plans had long benefited from AIM's noncompliance through inflated denial rates and increased profits.

122. Around the same time, CMS began to adjust payments to MA plans based on the quality ("star") rating of the plan. CMS rated the performance of each MA Plan on numerous metrics and assigned the plan a "star" rating for the year. Higher rated plans receive a higher capitation payment than the lower rated plans. 42 U.S.C. § 1395w-23(a)(3).

123. One of the metrics in the star ratings is initial coverage denials overturned on appeal. When appeals began to impact CMS's payment rates, insurance plans became increasingly sensitive to appeals and critical of AIM's noncompliant UM review process. The more requests AIM wrongly denied, the more appeals it generated, and the more wrongful decisions the insurance plans had to reverse on appeal. This hurt the insurance plans' star ratings, and ultimately their bottom line. By 2014, insurance plans increasingly pressured AIM to reform the system from which they had benefited for so long.

124. After the rejected January to April 2014 Medicare compliance experiment, AIM developed a modified review processes for Medicare requests. Under the leadership of Julie

Thiel, AIM created a purportedly "hybrid" review process that would improve AIM compliance with Medicare Rules, but fall short of actual, full compliance with Medicare Rules.

125. AIM implemented the "hybrid" review process for several MA plans from approximately September to December 2014. Again, AIM's denial rates plummeted to about 1%. AIM's denials and savings for its clients were so low that, as Anne Puksty, VP of Client Management outlined in an email on November 6, 2014, AIM planned to apologize to an insurance plan for the hybrid program and to pin the failure on "a mistake."

126. Further, when AIM attempted to explain and sell the "hybrid" review process to insurance plans, the plans rejected AIM's approach. Plans that had faced CMS audits and cost pressure from the new star ratings had little interest in AIM's allegedly semi-complaint "hybrid" review process. For example, in 2014, Defendant BCBS of North Carolina refused any AIM review process that relied on the AIM Guidelines. Other plans that had not faced the same CMS scrutiny, such as Defendant Regence, wanted to stay with the existing AIM UM model, even when AIM explained that the new review process was "the way "to be compliant with CMS coverage determinations."

127. With the "hybrid" review process floundering, and in light of ongoing compliance concerns, AIM abandoned the failed "hybrid" review process and began to develop yet another review model—the fourth in 2014 alone—for MA claims. The latest iteration was called the "hierarchical model," and was the only review process that contemplated actually looking at Medicare policies to review each MA request. AIM discussed routing all MA requests to dedicated MA reviewers, applying Medicare NCDs (but not LCDs), and using Medicare rules as the basis for some denials. AIM made plans to finally rollout this "hierarchical" review process

to some insurance clients starting on January 1, 2015. If it was implemented, this review process might have been closer to following some (but not all) Medicare Rules.

128. At the same time as AIM was preparing to become at least somewhat more compliant with Medicare Rules, AIM also continued to offer its traditional noncompliant UM review process for Medicare requests. AIM executives, including Christiane Shah, VP of Client Management, believed that some insurance plans that had not been subject to CMS audits might continue to choose the higher profits from the existing noncompliant UM review process. She was correct.

129. For example, on October 6, 2014, Defendant Regence of Idaho told AIM, including Christiane Shah, that it preferred to stay on the existing UM model rather than the "more compliant" hybrid model. Likewise, on October 10, 2014, Anne Puksty, AIM VP of Client Management, argued that for insurance plans "compliance risk will be taken under advisement and will be weighed against the business / financial risk" of giving up the savings AIM had been generating and that insurance plans had "already booked for 2015." In further correspondence on October 14, 2014, Ms. Puksty clarified that AIM would in fact permit the insurance plans to "have the ultimate decision about whether they choose to move to our compliant model," or continue using a review process from AIM that violated Medicare Rules.

130. Even with these changes in 2014, and as AIM claimed to develop new review processes, AIM was still so concerned about causing the insurance plans to violate Medicare rules that AIM executives, including Randy Hutchinson and Christiane Shah, discussed revising AIM's contracts with insurance plans, such as Defendants BCBS of Michigan and BCBS of North Carolina, to state that AIM was not responsible for the plans' violations of Medicare Rules.

131. Finally, while Dr. Nedza worked for AIM, and in spite of her continuous efforts to get AIM to comply with Medicare Rules, AIM never implemented a Medicare-compliant review process. During Dr. Nedza's tenure, AIM's awareness that it was violating Medicare Rules was continually subordinated to the drive to make greater profits.

4. Anthem Inc., AIM's parent company, condoned AIM's UM review process, but for a time refused to use it due to compliance concerns, until Anthem too relented in search of profits.

132. Anthem Inc., AIM's parent company, was aware of, endorsed, and profited from AIM's noncompliance with Medicare Rules.

133. AIM and Anthem executives regularly discussed AIM's UM review process, the fact that the process did not comply with Medicare Rules, and, in light of compliance concerns, whether Anthem insurance plans would use the AIM UM review process. Dr. Nedza participated in numerous conversations where AIM and Anthem executives discussed how AIM's review process violated Medicare Rules. On April 4, 2013, for example, she reported to Dr. Richard Frank, Anthem's National Staff Vice President and Medical Director for Medicare Advantage, that AIM's policy and procedure was to follow the internal AIM Guidelines to deny care, even when a procedure is specifically and expressly a "Covered Benefit" under Medicare Rules. Similarly, in mid-2014, Dr. Nedza spoke with Dr. Steve Friedhoff, Anthem's Senior Vice President of the Clinical Strategy and Programs, while at a meeting in San Francisco. He acknowledged that Anthem was aware that the AIM UM review process violated Medicare Rules.

134. Some Anthem executives, such as Anthem Vice President Dr. Alan Rosenberg tried to have Anthem take control of approving and revising the AIM Guidelines because the Guidelines as created by AIM violated Medicare Rules. AIM and its executives pushed back.

Ultimately, Anthem CEO Angela Braly resolved the dispute by permitting AIM to maintain control over the Guidelines and continue its very lucrative but noncompliant UM review process for MA plans.

135. These discussions occurred as part of Anthem's regular oversight of its subsidiary, AIM, but also during the years-long discussions about whether Anthem would use the AIM UM review process for the numerous large health insurance plans it owned.

136. From at least 2008 to 2011, Anthem, Inc. directed its insurance plans to use the AIM UM review process for Medicare requests. Anthem did so despite a CMS audit findings prior to 2008 that criticized an Anthem plan (through AIM) for ignoring Medicare Rules in the AIM review process.

137. Then, spurred by a further CMS audit of an Anthem insurance plan, Anthem decided in 2011 or 2012 that the AIM's practices were so improper that Anthem pulled its own MA insurance plans out of the full AIM UM review process, even though doing so meant giving up tens of millions of dollars in profits.

138. Anthem, however, allowed AIM to continue to sell the UM review processes to non-Anthem Medicare insurance plans, knowing that it was not Medicare compliant. Anthem did so to continue to reap the profits from AIM's revenue.

139. During the entire time Dr. Nedza worked for AIM, AIM executives campaigned to return Anthem MA insurance plans to the AIM UM review process, not only for the credibility and marketing boost AIM could claim from saying Anthem plans use the service, but for the tremendous revenue.

140. Finally, in late 2014, Dr. Richard Frank, Anthem's National Staff Vice President and Medical Director for Medicare Advantage and Dr. Steve Friedhoff, Senior Vice President of

Clinical Program and Strategy for Anthem, convinced Anthem corporate management to boost the bottom line of its insurance plans by returning its plans to the AIM UM review process. The decision to return to the AIM UM review process was approved by Anthem's top leadership, including Dr. Mary McCluskey (Anthem's Chief Medical Officer for Government Products).

141. Anthem simply decided the potential profits warranted the of risk being caught violating Medicare Rules. AIM executives discussed the compliance risk of Anthem's decision. CEO Brandon Cady told Dr. Nedza at the time in 2014 that he wanted to be sure that Anthem's "Mary McCluskey's name is on an email" approving the decision "so when we get caught [by CMS] it's on her." Mr. Cady wanted Anthem and Dr. McCluskey to face the criminal ramifications and responsibility if Anthem's insurance plans were barred from the MA program.

142. Despite years of concerns, Anthem never ordered, instructed, or caused its subsidiary AIM to comply with the law and follow Medicare Rules. Instead Anthem encouraged the fraudulent practices, all the while enjoying AIM's profits and profits AIM generated for Anthem's subsidiary plans.

5. Defendant Insurance Plans knew or recklessly disregarded the fact that AIM flouted Medicare's rules, and falsely certified compliance to Medicare.

143. The Defendant Insurance Plans who enjoyed the inflated profits that AIM generated on Medicare beneficiaries either knew or recklessly disregarded the fact that AIM's UM review process violated Medicare Rules.

144. The Defendant Insurance Plans chose to violate Medicare Rules to increase profits. The contracts between AIM and many of its insurance plan clients were clear that AIM would review and deny requests based on the "AIM guidelines and health plan medical policy," while ignoring Medicare Rules. AIM's violation of Medicare Rules was part of the discussion with insurance plan clients when AIM sold its review products. For example, in selling AIM UM

services to Independence Blue Cross, Christiane Shah, VP for Client Management, reported in an email to AIM executives that the "pushback" against AIM's UM review process comes from the insurance plan "compliance teams." But Ms. Shah explained that the AIM sales strategy was to convince the insurance plan "business decision makers" to "override the compliance concerns" to "take the compliance risk in return for CoC [Cost of Care] value" generated by hiring AIM.

145. Similarly, executives at Defendant BCBS of North Carolina discussed with AIM how AIM ignored Medicare Rules in its UM review process, and until late 2014 explicitly authorized AIM to continue to use the noncompliant UM review process and ignore Medicare coverage guidelines. Dr. Eugenie Komives, VP and Senior Medical Director with BCBS of North Carolina approved AIM's use of its UM review process for many years, knowing it was not in compliance with Medicare Rules. Only when BCBS of North Carolina was caught in a CMS audit in early 2014, and their appeals experience threatened the continuation of their capitation (premium) payments under CMS's star rating system, did BCBS of North Carolina relent and ask AIM to follow the law.

146. Similarly, employees at Defendant BCBS of Michigan raised concerns in 2014 about AIM's lack of compliance with Medicare Rules and improper Medicare denials. These concerns reached the point that, in December 2014, BCBS of Michigan threatened to self-report to CMS its own violation of Medicare Rules caused by accepting AIM determinations. Ultimately, AIM marketing executives, including Anne Putsky, "walked them off the cliff" and convinced BCBS Michigan not to do so.

147. Like Defendant BCBS of Michigan and Defendant BCBS of North Carolina, all of AIM's insurance plan clients received monthly statements from AIM regarding the rate of denials and amount of money saved, broken down by imaging test. Any insurance plan with

these statements were provided with notice that AIM produced denial rates which they knew, or acted in reckless with disregard to the fact that, the rates far in excess of what would be produced under Medicare Rules.

148. In addition, many of the Defendant Insurance Plans are corporate subsidiaries of Anthem, Inc., which was well aware of AIM's noncompliance with Medicare Rules as discussed above.

149. The Defendant Insurance Plans, directly through their interactions with AIM or through corporate parent Anthem Inc., or both, either knew or at the very least acted in reckless disregard of the fact that AIM's UM review process violated Medicare Rules. The Defendant Insurance Plans also knew they were obligated to ensure that Medicare Rules were being followed by AIM. Thus, when each Defendant Insurance Plan certified to Medicare that it would follow and was following Medicare Rules those certifications were knowingly false, and the requests for capitation payments were false claims to secure fraudulent payment from the government.

E. AIM's scheme enriched Defendants at the expense of Medicare beneficiaries.

150. AIM's UM review process caused Defendant Insurance Plans to deny Medicare beneficiaries coverage for services that should have been approved. Without pre-authorization, the Defendant Insurance Plans would not cover the imaging procedures. Without insurance coverage, Medicare beneficiaries were forced to either pay exorbitant out of pocket prices, or, more realistically for most, simply forgo the procedure.

151. This wrongful denial of Medicare coverage was particularly insidious for the imaging tests, because such tests are necessary to detect and monitor serious illnesses and develop timely and appropriate treatment plans for everything from broken bones to potentially

fatal diseases such as cancer and heart disease. AIM effectively denied not only, for example, a simple CT scan or PET scan, but all of the necessary and critical medical care that would be indicated by those studies.

152. Proper and legally compliant coverage determinations for insurance plans are essential to ensuring that Medicare beneficiaries receive all of the appropriate healthcare to which they are guaranteed under Medicare. AIM knowingly made wrongful denials that cheated Medicare beneficiaries out of care and cheated the government out of capitation payments. The Medicare beneficiaries received less care than the government purchased on their behalf, and less care than the Defendant Insurance Plans certified they would pay for.

153. AIM's review process inflated Defendant Insurance Plan profits by tens of millions of dollars each year. The Defendant Insurance Plans, and AIM, knew the profit from violating Medicare rules when they made the choice to ignore Medicare Rules and use AIM services because AIM provided the Defendant Insurance Plans with regular "value statements" to demonstrate the cost-savings that result from reliance on AIM UM review process.

154. The profits from cheating the Medicare Program and Medicare beneficiaries were split between AIM, which gets a fee for each insurance plan member each month, and the Defendant Insurance Plans, which were often guaranteed cost savings at least multiple times the fee AIM takes. It was a win-win system—for AIM and Defendant Insurance Plans, and for Anthem, the parent company to both AIM and many of the Defendant Insurance Plans—so long as AIM could find ways to deny enough patient care to hit the annual denial rate targets in its contracts. It was a lose-lose system for the Medicare beneficiaries and the government.

F. AIM's meritless denial of requests for pre-authorization caused the submission of False Claims to the Medicare Advantage program.

155. By providing non-compliant coverage determinations on behalf of the Defendant Insurance Plans, AIM and Anthem caused the Defendant Insurance Plans to present false or fraudulent claims for payment or approval to the federal government in violation 31 U.S.C. § 3729(a)(1)(A).

156. Defendant Insurance Plans must enter into contracts with CMS to participate in the MA program and receive government payments. In those contracts, the Defendant Insurance Plans certify that they will comply with all Medicare Rules. 42 U.S.C. § 1395w-27. Those certifications were false, because AIM's coverage determinations, made on behalf of the Defendant Insurance Plans, did not comply with Medicare Rules. Without this false certification, no Defendant Insurance Plan would receive a single payment under the MA program.

157. The Defendant Insurance Plans' certifications were knowingly and intentionally false, because the Defendant Insurance Plans knew or acted in reckless disregard of the fact that AIM violated Medicare Rules, as discussed above, and yet even after using the AIM UM review process, Defendant Insurance Plans continued the false certification to CMS.

158. The Defendant Insurance Plans cannot subcontract away their obligation under CMS regulations, and they remain expressly liable for the Medicare violations of their subcontractors. 42 CFR § 422.504(i).

159. Similarly, by inducing and facilitating its Defendant Insurance Plans' misrepresentations to the government regarding the nature of their coverage review and approval process, Anthem and AIM repeatedly and knowingly made or used or caused false statements or records to be made or used material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B).

160. By failing to provide coverage required under the MA program, Defendant Insurance Plans repeatedly presented false or fraudulent claims for payment or approval to the federal government in violation 31 U.S.C. § 3729(a)(1)(A) and repeatedly and knowingly made or used or caused false statements or records to be made or used material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B).

COUNT I

(Violations of 31 U.S.C. § 3729(a)(1)(A))

161. Relator-Plaintiff repeats and re-alleges paragraphs 1-160.

162. This Count is brought by Dr. Nedza in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. § 3729(a)(1)(A).

163. By virtue of the acts described above, among others, Defendants repeatedly and knowingly presented, or caused to be presented, false or fraudulent claim for payment or approval to the Center for Medicare and Medicaid Services.

164. By virtue of the acts described above, among others, Defendants have violated the False Claims Act by repeatedly and knowingly presenting or causing false or fraudulent claims to be presented to the Government for payment or approval.

165. Plaintiff United States, unaware of the falsity of the claims and/or statements or records, and in reliance on their accuracy, paid for claims that would otherwise not have been allowed.

COUNT II

(Violations of 31 U.S.C. § 3729(a)(1)(B))

166. Relator-Plaintiff repeats and re-alleges paragraphs 1-160.

167. This Count is brought by Dr. Nedza in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. § 3729(a)(1)(B).

168. By virtue of the acts described above, among others, Defendants repeatedly and knowingly made or used or caused false statements or records to be made or used that were material to a false or fraudulent claim.

169. Plaintiff United States, unaware of the falsity of the claims and/or statements or records, and in reliance on their accuracy, paid for claims that would otherwise not have been allowed.

PRAYER FOR RELIEF

WHEREFORE, Relator prays for entry of judgment awarding the following damages or relief to the following parties and against Defendants:

To the UNITED STATES GOVERNMENT:

1. Three times the amount of actual damages sustained by the United States Government;

2. A civil penalty of not less than $10,957 and not more than $21,916 for each false claim submitted to the United States Government, or a greater amount if allowed by law; and,

3. Prejudgment interest and all other applicable interest.

To the RELATOR:

1. The maximum amount allowed under 31 U.S.C. § 3730(d);

2. Reimbursement of all costs and expenses Relator incurs in connection with this action;

3. Reasonable attorneys' fees;

4. Expert witness fees;

4. All other costs of this action; and

5. All further relief the Court deems just and proper.

JURY DEMAND

Relator requests a jury trial on all claims that can be tried to a jury.

Dated: February 23, 2018

By:

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CERTIFICATE OF SERVICE

The undersigned, an attorney, certifies that she caused a copy of this **SECOND AMENDED COMPLAINT** to be served through CM/ECF system to counsel of record on Friday, February 23, 2018.

Respectfully submitted,

/s/ Juliet Berger-White
One of the Attorneys for
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